KANSAS DEPARTMENT OF HEALTH & ENVIRONMENT
Division of Health & Environmental Laboratories

STANDARDS FOR ACCREDITATION OF ENVIRONMENTAL LABORATORIES
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STANDARDS FOR ACCREDITATION OF ENVIRONMENTAL LABORATORIES

The following requirements shall serve as the basis for accreditation of environmental laboratories.

Part I - Definitions.

(1) "Accuracy" means the degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator.

(2) "Analytical Detection Limit" means the smallest amount of an analyte that can be distinguished in a sample by a given radiochemistry measurement procedure throughout a given confidence interval.

(3) "Batch" means environmental samples which are prepared or analyzed, or both, together with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one to 20 environmental samples of the same matrix, meeting the above mentioned criteria, and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch is composed of 20 environmental samples of the same matrix analyzed together with the same process and personnel, using the same lot(s) of reagents, and with a maximum time between the start of processing of the first and last sample in the batch to be 24 hours. An analytical batch can also be composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group and can include prepared samples originating from various environmental matrices, and can exceed 20 samples.

(4) "Blank" means an analyte free matrix used to monitor contamination during sampling, transportation, storage, or analysis.

(5) "Calibration" means the determination by measurement or comparison with a standard, the correct value of each scale reading on a meter, instrument, or other device.

(6) "Certified Reference Material (CRM)" means a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

(7) "Chain of custody" means an unbroken trail of accountability that documents the physical security of samples, data and records.

(8) "Confirmation" means the verification of the identity of a component through the use of an approach with a different scientific principle from the original method. These may include, but are not limited to:

Second column confirmation
Alternate wavelength
Derivatization
Mass spectral interpretation
Alternative detectors or
Additional cleanup procedures.

(9) "Environmental Detection Limits" means the lowest level at which a radio-nuclide in an environmental medium can be unambiguously distinguished for a given confidence interval using a particular combination of sampling and measurement procedures, sample size, analytical detection limit, and procedure. The EDL shall be specified for the 0.95 or greater confidence interval. The EDL shall be established initially and verified annually for each test method and sample matrix.

(10) "Laboratory control sample" means a known matrix spiked with the compound(s) representative of the target analytes.

(11) "Matrix" means a component or substance which contains the parameter of interest. The following matrix types are used for batch determination:

(A) Aqueous. Includes surface water, groundwater and wastewater effluents.
(B) Drinking water. Aqueous samples which are designated as public or private drinking water supplies or potential public or private drinking water supplies.
(C) Saline/Estuaries. Any aqueous sample from an ocean or estuary, or other natural source.
(D) Non-aqueous liquid. Organic liquids with less than 15 percent settleable solids.

(E) Biological Tissue. Any sample of biological origin such as fish tissue, shellfish, or plant material. Such samples shall be grouped according to origin.
(F) Solids. Includes soils, sediments, sludges and other matrices with greater than 15 percent settleable solids.
(G) Chemical waste. A product or by-product of a process that results in a matrix not defined above.
(H) Air. Whole gas or vapor samples including those contained in flexible or rigid wall containers and the extracted concentrated analytes of interest from a gas or vapor that are collected with a sorbent tube, impinger solution, filter, or other device.

(12) "Matrix spike" means an aliquot of sample spiked with a known concentration of target analyte(s). The spiking occurs prior to sample preparation and analysis.

(13) "Matrix spike duplicates" means intra-laboratory split samples spiked with identical concentrations of target analyte(s). The spiking occurs prior to sample preparation and analysis.

(14) "Method blank" means an analyte-free matrix to which all reagents are added in the same volumes or proportions as used in sample processing. The method blank should be carried through the complete sample preparation and analytical procedure.

(15) "Method detection limit (MDL)" means the minimum concentration of a substance that can be measured and reported with a 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix type containing the analyte.

(16) “Minimum significant difference” means the statistical measurement between the control and test concentration.

(17) “NIST” means the National Institute of Standards and Technology of the U.S. Department of Commerce.

(18) “Precision” means the degree to which a set of observations or measurements of the same property obtained under similar conditions, conform to themselves; a data quality indicator. Precision is expressed as standard deviation, variance or range, in either absolute or relative terms.

(19) “Reference Material” means a material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

(20) "Reference Standard" means a standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

(21) "Traceability" means the property of a result of a measurement whereby it can be related to appropriate standard, generally international or national standard, through an unbroken chain of comparisons.

(22) "Verification" means confirmation by examination and provision of evidence that specified requirements have been met. In connection with the management of measuring equipment, verification provides a means for checking that the deviations between values indicated by a measuring instrument and corresponding known values of a measured quantity are consistently smaller than the maximum allowable error defined in a standard, regulation or specification peculiar to the management of the measuring equipment. The result of verification leads to a decision either to restore in service, to perform adjustment, to repair, to downgrade, or to declare obsolete.

(23) "Work Cell" means a well defined group of analysts that together perform the method analysis.

Part II - Personnel requirements.

Each laboratory shall have personnel with the education, training and technical knowledge and experience to perform all analyses and conduct all quality assurance activities for which the laboratory is to be accredited. Each laboratory shall be accredited only after presentation of satisfactory documentation to the department regarding education and work experience.

(1) Laboratory Director. Each laboratory shall appoint a laboratory director. The laboratory director is responsible for the technical and scientific oversight of all laboratory activities.

(A) Qualifications for laboratory director of a chemistry laboratory shall be as follows:

(i) A bachelors degree in chemistry, environmental science, biological sciences, physical sciences or engineering, with a minimum of 24 college semester credit hours in chemistry and at least two years of experience in environmental analysis. A masters or doctoral degree in one of the above sciences may be substituted for one year of experience.
(ii) For laboratories engaged in inorganic analysis only, excluding metals analysis, the laboratory director may be a person with an associate's degree in chemistry or environmental science or equivalent with a minimum of 16 college semester credit hours in chemistry and two years of experience performing inorganic environmental analysis.

(B) Qualifications for laboratory director of a microbiology and whole effluent toxicity laboratory shall be as follows:

(i) A bachelors degree in microbiology, biology, chemistry, or environmental science, with a minimum of 16 college semester credit hours in microbiology and biology, and two years experience in environmental analysis. A masters or doctoral degree in one of the above sciences may be substituted for one year of experience.
(ii) For laboratories engaged in microbiological analysis limited to coliform and heterotrophic plate count testing, the laboratory director may be a person with an associate degree in science or the equivalent with at least four semester credit hours in microbiology and one year of experience in environmental analysis.

(C) Qualifications for laboratory director of a radiochemistry laboratory shall be as follows:

(i) A bachelors degree in chemistry or physics with two years of experience, one year in the supervision of environmental radiochemistry. A masters or doctoral degree in one of the above sciences can be substituted for one year of experience.

(D) A valid treatment plant operator's certificate can be substituted for the above qualifications for a laboratory director of a drinking water or wastewater treatment facility engaged in the analysis of environmental samples collected within the state.

(E) One year of supervised experience in environmental analysis can be substituted for the above qualifications for laboratory director of an industrial waste facility when the laboratory only analyzes samples collected within the state.

(F) When the laboratory engages in more than one analytical category (chemistry, microbiology, whole effluent toxicity, and radiochemistry), one or more persons may compliment the laboratory director provided that each meets the applicable qualifications for the analytical category as specified in paragraph (1) of this section.

(G) Persons working in the capacity of laboratory director on the effective date of K.A.R. 28-15-36 may continue to qualify as the laboratory director.

(2) Quality Assurance Officer (QAO). Each laboratory shall appoint a QAO. The QAO is the person responsible for the laboratory's quality assurance program and it's implementation.

(A) The QAO shall review laboratory quality control data, conduct annual internal laboratory audits, and notify management of deficiencies found in the laboratory's quality assurance program. The QAO shall be free from internal and external influences when evaluating data and conducting audits. The QAO shall have training or experience, or both in quality assurance/quality control procedures and shall have knowledge of the approved analytical methods and quality assurance program requirements. The QAO shall maintain the laboratory's quality assurance documents up to date.

(B) The QAO duties and responsibilities can also be carried out by the laboratory director when staffing is limited.

(C) The QAO shall have access to laboratory management.

(3) Responsibilities of laboratory management. The laboratory management shall have the authority and resources needed to discharge the following duties:

(A) The laboratory management shall be responsible for ensuring the quality of data produced by the laboratory and for documenting all analytical and operational activities of the laboratory.

(B) Laboratory management shall establish the minimum level of qualifications, experience, and skills necessary for all positions in the laboratory.

(C) The laboratory management shall ensure that the training and performance of the laboratory personnel is kept up to date.

(i) Analyst training and performance shall be considered up to date when the following items are documented:

- Analyst is using the latest version of the laboratory's quality assurance documents;
- training on equipment, technics, or procedures;
- training in ethical and legal responsibilities;
- demonstration of initial performance (See Appendix A, Demonstration of Capability) and continuing performance.

(ii) Analyst continued performance shall be considered up to date when at least once per year one of the following items is documented:

- Acceptable performance of a blind sample;
- another demonstration of capability;
- successful analysis of a blind performance sample on a similar method using the same technology;
- analysis of at least four consecutive laboratory control samples with acceptable levels of precision and accuracy; or
- if one of the above can not be performed, the analysis of environmental samples that have been analyzed by another trained analyst with statistically indistinguishable results.

(D) The laboratory management shall assure all sample acceptance criteria are verified and samples are logged into the tracking system and properly labeled and stored.

(E) The laboratory management ensures all personnel employed by the laboratory are supervised by persons familiar with the laboratory operations.

(F) The laboratory management shall conduct annual reviews of the laboratory's quality assurance program.

(G) The laboratory management shall nominate a deputy when the laboratory director is absent from the laboratory for more than 15 days. The laboratory management shall notify the department when the absence of the laboratory director exceeds 65 days.

Part III - Laboratory facilities.

Each laboratory conducting chemical, microbiological, radiochemical or biological analyses shall meet the following requirements:

(1) The laboratory's accommodations, test areas, energy sources, lighting, heating and ventilation shall be as needed for the proper performance of tests. Measures shall be taken to ensure good housekeeping.

(2) The facilities in which the analysis is performed shall not have an adverse impact on the test results.

(3) The laboratory shall document the facility's environmental conditions as required by the approved method.

(4) Where safety practices are included in an approved method, they shall be strictly followed.

(5) Access to analytical and sample storage areas shall be controlled. There shall be separation between areas to avoid cross contamination.

(6) Sufficient work space shall be available to ensure unencumbered work area.

Part IV - Laboratory equipment, reference materials, reagents, supplies, and reference standards

All equipment, reagents, supplies, reference standards and reference materials necessary for laboratory analyses shall be on-site for the specific analysis for which the laboratory is to be accredited.

(1) Laboratory equipment and reference materials.

(A) All equipment shall be properly maintained. Procedures for maintenance of equipment shall be documented. Maintenance and repairs shall be documented.

(B) Defective equipment or parts shall be removed from service and labeled until repaired. The effect of the defective equipment on previous calibrations or tests shall be examined by the laboratory. Equipment or parts shall not be put back in service until the laboratory demonstrates that its functioning correctly.

(C) When appropriate, equipment and reference material shall be labeled, marked or identified to indicate calibration status.

(2) Laboratory Support Equipment. Laboratory support equipment are devices necessary to support laboratory operations.

(A) General requirements for laboratory support equipment are as follows:

(i) Laboratory support equipment shall be maintained in working order. The records of all repairs and maintenance activities shall be kept;
(ii) support equipment shall be calibrated or verified, or both, before being put into service, and on a continuing basis;
(iii) the laboratory shall have an established procedure for the calibration and verification of its support equipment;
(iv) when calibrations are outside specifications required for the application for which this equipment is used, the support equipment shall be removed from service or the laboratory shall maintain records of established correction factors for the correction of all measurements made with the equipment;
(v) records shall be maintained to document instrument performance;
(vi) prior to use on each working day, balances, ovens, refrigerators, freezers, incubators, and water baths shall be checked with reference materials in the

expected use range. The acceptability for use of these support equipment shall be based on the needs for the application or test. Checks shall be documented.

(B) Specific requirements for laboratory support equipment are as follows:

(i) Balances.

- Balances shall be calibrated and serviced once per year. Service date shall be posted on the balance;
- prior to each day's use, balances shall be checked with NIST traceable reference weights in the expected use range. This check shall be documented.

(ii) Temperature measuring devices.

- All glass and electronic thermometers used by the laboratory shall be checked once per year and dial thermometers once per quarter, at the temperature used, against a reference NIST thermometer;
- the thermometer shall be labeled with the correction factor(s) (when used), and the date the check was conducted.

(iii) Refrigerators, Freezers, and BOD incubators.

- Thermometers shall be immersed in liquid to the appropriate immersion line;
- the thermometers shall be graduated in increments of 1°C or less;
- temperature shall be recorded each working day in use;
- continuous temperature monitoring devises can be used in place of glass thermometers.

(iv) Volumetric dispensing devices. Automatic or digital type pipettes (if used when quantitative results are dependent on their accuracy) shall be checked for accuracy on a quarterly basis using reagent water and an analytical balance. Checks shall be documented. Glass microliter syringes used by the laboratory that were purchased with an accuracy certificate do not need checks, certificates shall be part of the laboratory records.

(v) Autoclaves/Sterilizers.

- Date, content, sterilization time, temperature, total cycle time, and analyst's initials shall be documented for each cycle.
- The laboratory shall use a maximum-temperature-registering thermometer or continuous temperature recording device with each autoclave cycle. Temperature readings shall be documented by the laboratory. Biological indicators shall be used on a monthly basis. When maximum-temperature-registering thermometer or continuous temperature recording devices are not available, biological indicators shall be used on a weekly basis.
- For chemical tests the laboratory shall document the temperature, the cycle time, pressure of the autoclave, date, analyst's initials and the sample identification.
- Hot air ovens used for sterilization shall be capable of maintaining a stable temperature of 170°C - 180°C for at least two hours; Date, content, sterilization time, temperature, and analyst's initials shall be documented.

(vi) Microbiological incubators, and water baths.

- Thermometers in each unit shall be immersed in liquid to the appropriate immersion line;
- the thermometers shall be graduated in increments of 0.5 °C (0.2 °C increments for test which are incubated at 44.5 °C) or less;
- temperature of incubators and water baths shall be recorded twice a day for each day in use with readings separated by at least four hours;
- continuous temperature monitoring devices can be used in place of glass thermometers.

(vii) Conductivity meters, oxygen meters, and pH meters. These instrument shall be calibrated according to the method requirement. Calibrations shall be documented.

(viii) Mechanical timers shall be checked regularly against another accurate timing device to ensure accuracy. Checks shall be documented.

(3) Reagents and supplies

(A) Glassware cleaning and storage procedures shall be done so they meet the sensitivity needed for the analysis. Any cleaning or storage requirements specified in the approved test procedure shall be followed. Procedures for glass cleaning and storage shall be in place.

(B) Analytical reagent grade materials, if available, shall be used by the laboratory. The purity of reagents used by the laboratory shall be documented.

(C) The laboratory shall not use prepared reagents, standards, or purchased chemicals outside the expiration date of the material unless verified by the laboratory.

(D) All stock and standard solution containers shall be labeled with content, preparation date, concentration, and initials of analyst.

(E) Compressed gases shall meet the requirements specified in the approved method.

(F) For the preparation of dilutions, reagents, standards, and rinsing of glassware, the laboratory shall use a water source that meets the required standards of quality for each type of analysis. The quality of water shall be monitored and documented.

(4) Reference standards.

(A) Reference standard of measurement (such as class S weights or equivalent, or thermometers) shall be used for calibrations only.

(B) Reference standard of measurement shall be calibrated by a body that can provide, where possible, traceability to international or national standard of measurement. When a calibration certificate is available, it shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification. The laboratory shall keep these certificates as part of their records.

(C) The laboratory shall have a program in place for the calibration and verification of reference standards.

Part V - Sample collection, preservation, holding time, and handling.

Each sample shall be properly collected, handled, preserved, stored and analyzed within the required holding time.

(1) Sample collection, preservation, and holding time.

(A) Sample volume, container, preservation, and holding time shall be in the manner prescribed by the EPA regulations promulgated under the clean water act, the safe drinking water act and the resource conservation and recovery act.

(B) When the laboratory is responsible for sample collection, the sample collector shall be trained in sampling procedures. A written sampling protocol with specific sampling instructions shall be available to each sample collector.

(C) A sample collection form shall be completed for each sampling event. This form shall contain sampling location, date and time of collection, collector's name, method of preservation, and special remarks concerning the sample.

(D) Each laboratory shall have available an acceptable procedure to track samples from collection through analysis and disposal.

(2) Handling of sample.

(A) The laboratory shall have a documented system for the unique identification of samples received at the laboratory. The system shall include identification for all, sub-samples, extracts, and digestates.

(i) Each sample container shall be labeled with an unique identification code (the container physical characteristic is not an acceptable means of identification);
(ii) The identification code shall maintain a unique link to the field sample code when in use by the laboratory or their clients;
(iii) The sample identification shall maintain a unique link to all laboratory activities related to that sample.

(B) Each laboratory shall have a sample acceptance procedure. This procedure shall be made available to sample collectors. At a minimum, the sample acceptance procedure shall consider the following areas:

(i) Completeness of sample collection forms;
(ii) procedures used for samples showing signs of damage or contamination;
(iii) appropriate use of sample labels (such as water resistant) and use of indelible ink;
(iv) use of appropriate sample containers, adequate volume, preservation, and holding time as required in paragraph (1)(A) of this section.

(C) Upon receipt in the laboratory, the sample integrity and preservation shall be checked and recorded.

(i) Temperature of samples requiring thermal preservation shall be checked and recorded; All samples which require thermal preservation shall be considered acceptable if the arrival temperature is either within ± 2°C of the required temperature or the method specified range. For samples with a specified temperature of 4°C , samples with a temperature ranging from just above the freezing temperature of water to 6°C shall be acceptable. Samples that are hand delivered to the laboratory immediately after collection may not meet this criteria. In these cases, the samples shall be considered acceptable if there is evidence that the chilling process has begun such as arrival on ice.
(ii) Chemical preservation shall be checked prior to or during sample preparation or analysis using readily available techniques. Results shall be recorded.
(iii) When the sample received does not meet the sample acceptance requirements, the laboratory shall request or collect another sample or obtain permission from the client to continue with the analysis. The condition of the sample shall be documented along with any conversations or correspondence with the client concerning the final disposition of the sample.
(iv) Samples analyses by the laboratory not meeting the sample acceptance requirements shall be qualified on the final report.

(D) Upon sample receipt, the laboratory shall record the following information, where applicable:

(i) Sample identification;
(ii) client/project identification, when applicable;
(iii) signature or identification of the person recording the information;
(iv) field identification code;
(v) analysis requested;
(vi) date and time of sample collection and date and time of sample receipt; and

(vii) any comments resulting from rejection of the sample.

(E) The laboratory shall store samples, sub-samples, extracts, and digestates according to the specified conditions in the approved methodology. The laboratory shall have documented procedures and appropriate facilities to avoid deterioration, contamination, or damage to the sample during storage, handling, preparation, and testing; any relevant instructions provided with the item shall be followed Where items have to be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored and recorded.

(i) Samples, sample fractions, extracts, leachates, and other sample preparation products shall be stored according to the conditions specified by preservation protocols:

- Samples which require thermal preservation shall be stored under refrigeration which is ± 2°C of the specified preservation temperature unless method specific criteria exist. For samples with a specified storage temperature of 4°C, storage at a temperature above the freezing point of water to 6°C shall be acceptable.
- Samples shall be stored away from all standards, reagents, food and other potentially contaminating sources. Samples shall be stored in such a manner to prevent cross contamination.

(ii) Where a sample or portion of the sample is to be held secure (for example, for reasons of record, safety or value, or to enable check calibrations or tests to be performed later), the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions of concern.

(F) The laboratory shall have standard operating procedures for disposal of samples, sub-samples, extracts, digestates, and preparation products.

(G) For each sample, sub-sample, extract, or digestates that is forwarded to another laboratory for analysis, an appropriate chain of custody form shall be maintained.

(H) When a state environmental program, a federal program, or a client require or request a complete accountability for the physical security of the sample, the laboratory shall be required to meet the following additional custody conditions:

(i) A sample is in someone's custody if:

- It is in one's actual physical possession;
- it is in one's view, after being in one's physical possession;
- it is in one's physical possession and then locked up so that no one can tamper with it; or
- it is kept in a secured area, restricted to authorized personnel only.

(ii) The custody records shall account for all time periods associated with the samples.

(iii) The custody records shall identify individuals who physically handled the sample.

(iv) In order to simplify record-keeping, the number of people who physically handle the sample should be minimized. A designated sample custodian, who is responsible for receiving, storing and distributing samples is recommended.

(v) The custody records are not limited to a single form or document. However, organizations should attempt to limit the number of documents that would be required to establish custody records.

(vi) Complete accountability of the sample shall begin at the point established by the state, or federal oversight program, or by the client requesting the work. This may begin at the point that cleaned sample containers are provided by the laboratory or the time sample collection occurs.

(vii) The chain of custody forms shall remain with the samples during transport or shipment.

(viii) If shipping containers and/or individual sample containers are submitted with sample custody seals, and any seals are not intact, the lab shall record this condition.

(ix) Mailed packages should be registered with return receipt requested. If packages are sent by common carrier, receipts should be retained as part of the permanent custody documentation.

(x) Once received by the laboratory, laboratory personnel are responsible for the care and custody of the sample and must be prepared to testify that the sample was in their possession and view or secured in the laboratory at all times from the moment it was received until the time that the analyses are completed or the time of sample disposal.

(xi) Custody records shall include:

- Time and date of each transfer or handling;
- signatures of all personnel who physically handle the sample(s);
- all information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting; and
- common carrier documents.

(xii) Access to the sample and subsamples extracts, and digestates shall be controlled and documented:

- A clean, dry, isolated room, building, and/or refrigerated space that can be securely locked from the outside must be designated as a custody room.
- Where possible, distribution of samples to the analyst performing the analysis must be made by the custodian(s).
- The laboratory area must be maintained as a secured area, restricted to authorized personnel only.
- Once the sample analyses are completed, the unused portion of the sample, together with all identifying labels, shall be returned to the custodian. The returned sample shall be retained in the custody room until permission for sample disposal is obtained.

(3) Transfer of samples, sub-samples, digestates or extracts to another party are subject to all of the requirements listed in this section for complete accountability of sample.

(4) Sample Disposal.

(A) Disposal of the physical sample shall occur only with the concurrence of the affected legal authority, sample data user and/or submitter of the sample.

(B) All conditions of disposal and all correspondence between all parties concerning the final disposition of the physical sample shall be recorded and retained.
(C) Records shall indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility, or sample returned to client), and the name of the individual who performed the task.

Part VI - Analytical methods.

(1) Each drinking water sample analyzed under the safe drinking water act shall be analyzed in accordance with methods and method detection limits approved by the laboratory accreditation officer as required by the safe drinking water act.

(2) Each environmental water sample analyzed under the clean water act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the clean water act.

(3) Each solid and hazardous waste sample analyzed under the resource conservation and recovery act shall be analyzed in accordance with methods approved by the laboratory accreditation officer as required by the resource conservation and recovery act.

(4) Prior to method approval by the department and implementation of the method by the laboratory for the analysis of samples, the laboratory shall prepare a demonstration of capability in accordance with method specification, or when not available, in accordance with guidelines provided by the department (See Appendix A). Demonstration of capability shall be repeated each time there are changes in personnel, methodology, or significant changes in instrumentation. Demonstration of capability shall be documented. The documentation shall include a demonstration of capability certificate provided by the department (See Appendix)

(5) For analysis of environmental samples for permit or contract requirements for which the use of an EPA promulgated method is not a requirement, the laboratory shall summit to the department for approval the procedure used. When applicable, the laboratory shall make the test method available to the client. The following requirements shall be met for approval:

(A) The laboratory shall validate the method in accordance with guidelines provided by the department;

(B) the procedure shall be fully documented by the laboratory; and

(C) all data necessary to reproduce the analytical results shall be retained by the laboratory.

(6) When the demonstration of capability is repeated due to changes in personnel, the demonstration of capability documentation shall become part of the employee’s training records.

(7) Laboratories using work cells shall perform demonstration of capability or method validation as a group. When a member of a work cell changes, the cell as a group shall demonstrate acceptable performance with the first four quality control batches analyzed by the group. If the batch acceptance fails, a new demonstration of capability or method validation shall be performed by the work cell. When the entire work cell changes, a new demonstration of capability or method validation shall be conducted by the group. The work cell performance shall be documented in each member's training records.

Part VII - Laboratory quality assurance program

Each environmental laboratory shall establish and maintain an effective quality assurance program which states the laboratory's policies and procedures. The quality assurance program shall be documented in the laboratory's quality assurance manual and/or related quality documents. The quality assurance manual, quality documents and standard operating procedures shall be available to, understood by, and implemented by laboratory personnel.

(1) Quality assurance manual and related quality assurance documents. The following are the minimum areas that shall be included in the quality assurance manual and/or related quality documents:

(A) Title page. The title page shall include:

(i) Document title;

(ii) laboratory's name and address;

(iii) name signature and telephone number of the individual responsible for the laboratory;

(iv) name and signature of the QAO;

(v) effective date; and

(vi) when applicable, identification of all organizational units covered by the manual.

(B) Table of contents.

(C) Quality policy statement. The statement shall include objectives and commitments of management.

(D) Organization and management structure of the laboratory, and its relationship to its parent organization. This shall also include the relationship between management, technical operations, support services and the quality management system.

(F) Mechanisms for ensuring the laboratory reviews all new work to ensure it has the appropriate facilities and resources before commencing such work.

(G) Procedures for record retention. This section shall also include a procedure for maintenance of documentation through a document control system which ensures that all documents clearly indicate the time period during which the document was in force.

(H) Job descriptions of key staff positions, and reference to job description of other laboratory staff.

(I) A listing of equipment, and reference materials. Reference to procedures for calibration, verification, and maintenance. A description of facilities and services used by the laboratory shall be included.

(J) Procedures for achieving traceability of measurement shall be defined.

(K) Procedures for dealing with complaints.

(L) Procedures for protecting client confidentiality and proprietary rights, if applicable.

(M) Procedures for establishing personnel are adequately experienced and are receiving the needed training in their duties.

(N) Procedures for the handling of samples.

(O) Reference to the test procedures used for calibration and or verification.

(P) A list of analytical tests and parameters performed by the laboratory shall be compiled.

(Q) Verification practices used by the laboratory such as use of reference materials, internal quality control procedures, and proficiency testing studies.

(R) Reporting procedures and format shall be included. Procedures shall also include measures to ensure reported data is free from errors.

(S) Corrective action. Sample results shall be reported only if all QC measures are acceptable. If the laboratory reports data associated with failed QC, the data shall be

reported with appropriate qualifier(s). Details of any measures to be taken when departures from procedures, policies, quality controls, or regulations occurs shall be described. The laboratory's arrangements for exceptionally permitting departures from procedures, policies, or quality controls shall be specified. These procedures shall include but are not limited to the following:

(i) identification of the individual(s) responsible for assessing QC;

(ii) identification of individual(s) responsible for initiating and/or recommending corrective actions;

(iii) define how the analyst should treat a data set if the associated QC measurements are unacceptable;

(iv) specify how out of control situations and subsequent corrective actions are to be documented; and

(v) specify procedures for management and QAO to review corrective action reports.

(T) Procedures for audits and data review.

(i) The laboratory shall have procedures for annual internal audits and for management reviews of the quality assurance program. The internal audit shall be conducted to verify that the laboratory operations continue to comply with the laboratory's quality assurance program. The internal audit shall be conducted by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

(ii) A review of the quality assurance program shall be completed by management to evaluate its continuing suitability and effectiveness and make any necessary changes or improvements. The annual review shall take into account the outcome of recent internal audits, on-site assessments by external bodies, the results of proficiency tests, any changes in the volume and type of work undertaken, feedback from clients, corrective actions and other relevant factors.

(iii) All audits and review findings and any corrective actions that arise from them shall be documented. Laboratory management shall ensure that corrective

actions are discharged within the agreed time frame. Immediate corrective action shall be taken when audit findings cast doubt on the correctness or validity of the calibrations or test results. Clients shall be notified immediately, in writing, when their work is affected by the findings from an internal audit.

(2) Standard Operating Procedures. The laboratory shall maintain standard operating procedures that accurately reflect all phases of current laboratory activities. Procedures shall consist of copies of published methods or standard operating procedures written by the laboratory. Any modifications made to the published method shall be documented. Each SOP shall indicate the effective date, the revision number, and the signature of approving individual(s). Procedures for conducting analytical tests shall be available for each accredited method. Each procedure shall include or reference where applicable the following items:

(A) Identification of the test method;

(B) Applicable matrix or matrices;

(C) Detection limit;

(D) Scope of the test method;

(E) Summary of the test method;

(F) Definitions;

(G) Interferences;

(H) Safety;

(I) Equipment and supplies;

(J) Reagents and standards;

(K) Sample collection, preservation, shipment and storage;

(L) Quality control;

(M) Calibration and standardization;

(N) Procedure;

(O) Calculations;

(P) Method performance;

(Q) Pollution prevention;

(R) Data assessment and acceptable criteria for quality control measures;

(S) Corrective actions for out-of-control or unacceptable data;

(T) Waste management;

(U) References; and

(V) Tables, diagrams, flowcharts and validation data.

Part VIII - Calibration

The laboratory shall follow instrument calibration requirements as specified by the mandated method. When the mandated method does not specify the calibration requirements, the laboratory shall establish calibration procedures. The calibration procedures shall include the following minimum requirements:

(1) Initial Instrument Calibrations:

(A) The initial instrument calibration procedures shall be referenced or described in the laboratory's written standard operating procedure.

(B) Sufficient raw data shall be retained for the reconstruction of the initial instrument calibration. Records shall include the following (where applicable):

Calibration date;
Test method;
Instrument;
Analysis date;
Each analyte name;
Concentrations;
Response; and
Calibration curve or response factor.

(C) Sample results shall be quantitated from the initial instrument calibration.

(D) All initial instrument calibrations shall be verified with a standard obtained from a second source and traceable to a national standard (when available).

(E) Criteria for the acceptance of an initial instrument calibration shall be established.

(F) When initial instrument calibration results are outside of the established acceptance criteria, corrective action shall be performed. The laboratory shall not report data associated with the unacceptable initial instrument calibration.

(G) When the laboratory reports sample results not bracketed by initial calibration standards, the sample shall be qualified in the report as having less certainty. The lowest

calibration standard used in the initial calibration shall be above the laboratory's detection limit.

(H) Calibration standards shall include concentrations at or below the regulatory limit unless these concentrations are below the laboratory's demonstrated detection limit.

(I) When the mandated method does not specify the number of calibration standards, the minimum number is two, not including blanks or a zero standard. Where applicable, the laboratory shall have a standard operating procedure for the determination of the number of points needed for initial instrument calibration.

(2) Continuing Instrument Calibration Verification. When an initial instrument calibration is not performed on the day of analysis, the validity of the initial calibration shall be verified prior to sample analyses by a continuing instrument calibration verification with each analytical batch.

(A) The continuing instrument calibration procedures shall be referenced or described in the laboratory's written standard operating procedure.

(B) A continuing instrument calibration verification shall be repeated at the beginning and end of each analytical batch. The concentrations of the calibration verification shall be varied within the established calibration range. When the laboratory uses internal standards, only one concentration per internal standard shall be necessary.

(C) Sufficient raw data shall be retained for the reconstruction of the continuing instrument calibration verification. Records shall include the following (where applicable):

Calibration date;
Test method;
Instrument;
Analysis date;
Each analyte name;
Concentrations;
Response;
Calibration curve or response factor.

(D) Criteria for the acceptance of a continuing instrument calibration verification shall be established.

(E) When the continuing instrument calibration verification results obtained are outside established acceptance criteria, corrective actions shall be performed. If routine corrective action procedures fail to produce a second consecutive (immediate) calibration verification within acceptable criteria, then either the laboratory has to demonstrate performance after corrective action with two consecutive successful calibration verifications, or a new initial instrument calibration shall be performed. If the laboratory has not demonstrated acceptable performance, sample analyses shall not occur until a new initial calibration curve is established and verified. However, the laboratory may choose to report data from samples associated with an unacceptable calibration verification as qualified data when the following special conditions occur:

(i) When the acceptable criteria for the continuing calibration verification are exceeded high, and there are associated samples that are non detects, then those no-detects may be reported. Otherwise the samples affected by the unacceptable calibration verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

(ii) When the acceptance for the continuing calibration verification are exceeded low, those samples results may be reported if they exceed a maximum regulatory limit/decision level. Otherwise the samples affected by the unacceptable verification shall be re-analyzed after a new calibration curve has been established, evaluated and accepted.

Part IX - Quality Control

Quality controls used by the laboratory shall be part of the laboratory's analytical procedures and shall be followed by the laboratory personnel performing the analysis.

(1) Chemical testing. The following are the minimum quality control requirements for chemical testing:

(A) Method Blanks. Method blanks shall be performed to demonstrate the analytical system is not contaminated. When the result of a method blank exceeds the quantitation limit and the blank concentration is greater than 1/10 of the measured concentration of any sample in the associated batch, or when the method blank is 1/10 of the regulatory limit, the laboratory shall minimize or eliminate the contamination problem (when possible) and determine the effect of a contaminated method blank on the samples tested. Any samples affected by a contaminated method blank shall be re-analyzed (when possible) or sample results shall be qualified.

(B) Matrix spikes. Matrix spikes shall be used to determine analytical accuracy and potential matrix interference. Percent recovery shall be calculated by the laboratory and acceptance criteria shall be established per matrix. Sample result shall be qualified when matrix spike recovery is outside the laboratory's acceptance criteria. When applicable, matrix spikes shall be rotated among clients.

(C) Laboratory control samples. Laboratory control samples shall be used to determine the accuracy of the analysis and batch acceptance. The laboratory shall calculate percent recovery and establish acceptance criteria. Matrix spikes can be used in place of laboratory control samples provided the laboratory uses acceptable criteria as stringent as the laboratory control samples.

(D) Matrix spike duplicates or laboratory duplicates. Matrix spike duplicates or laboratory duplicates shall be used to determine analytical precision. Relative percent difference or percent difference shall be calculated by the laboratory. Acceptance criteria shall be established. Sample result shall be qualified when relative percent difference or percent difference is outside the laboratory's acceptance criteria. When applicable, matrix spikes duplicates or laboratory duplicates shall be rotated among clients.

(E) Surrogates. For the analysis of organic compounds, surrogate compounds shall be spiked into each sample, each standard, and each blank. The laboratory shall qualify samples producing low surrogate recoveries.

(F) Method blanks, matrix spikes, laboratory control samples, and matrix spike duplicates or laboratory duplicates shall be performed at a frequency of one per batch.

(G) When the method does not specify the spiking components for the laboratory control sample and matrix spikes, the laboratory shall spike all reportable components. When the method included a long list or incompatible components, at least 10 percent of the reportable components shall be spiked in the LCS and MS. The selected spiking components shall be representative of all chemistries, elution patterns, and masses. Where applicable, the laboratory shall include permit specified components and other client requested components. The laboratory shall ensure that all reported components are used in the spikes within a two year time period.

(H) Detection Limits shall be calculated according to method specifications. When the method does not specify detection limits protocol, the laboratory shall:

(i) Determine detection limits initially and each time there is a significant change in the test method or instrument;
(ii) determine detection limits in a matrix free of target analytes or interferences or in the matrix of interest;
(iii) include all processing steps of the analytical procedure;
(iv) fully document the determination of the detection limits; and
(v) establish procedures to tie detection limits with quantitation limits.

(I) Selectivity. For the analysis of organic compounds, the laboratory shall develop and document acceptance criteria for retention time windows as determined by the approved method. When mass spectrometers are used for the analysis of samples, the laboratory shall develop and document acceptance criteria for mass tuning. Confirmation is required for all positive results on samples from locations where previous data is not available. Confirmation is not required when mass spectrometers are used for the analysis or when the client makes written stipulation.

(J) Matrix spikes and determination of detection limits are not required when determining physical properties or when spiking material is not available.

(2) Microbiological testing. The following are the minimum quality control requirements for microbiological testing.

(A) Membrane filtration blanks. Filtration blanks (sterile water) shall be preformed to demonstrate that the analytical system is not contaminated. Filtration blanks shall be run at the beginning, and end of each filtration batch and with every 10 samples.

(B) Sterility checks. Sterility checks shall be run on every lot of commercially prepared media, lot of commercially prepared rinse water, buffer water or presterile sample containers and every batch of laboratory prepared media, rinse water, buffer water and every sterilization batch of sample bottles.

(C) Microbiological controls.

(i) Known pure culture controls of a positive reaction shall be run at least monthly on each lot of media.
(ii) If a known positive result of the appropriate organism occurs during the month the above listed control is not required.
(iii) A known pure culture control of negative reaction shall be run at least monthly on each lot of media.

(D) Test variability / Reproducibility. Duplicates shall be preformed on at least 5 % of suspected positive samples.

(E) Method evaluation. A laboratory shall demonstrate proficiency with a test method prior to the first use of the method by the laboratory.

(F) Quality of standards, reagents and media.

(i) The laboratory shall retain all certificates of quality supplied by a manufacture for all prepared media, or media ingredients. Records of media type, lot number, date received and pH verification shall be retained by the laboratory.
(ii) Laboratory grade quality water used in the preparation of media, solutions, rinse water or buffer water shall be tested and meet the following criteria:

Test	**Monitoring Frequency**	**Limit**
Chemical test:		

Conductivity	Continuously or with each use	>0.5 megohms/cm resistance or < 2 umhos/cm at 25 °C
pH	With each use	5.5 - 7.5
Heavy Metals, single (Cd, Cr, Cu, Ni, Pb, and Zn)	Annually	< 0.05 mg/L
Heavy metals, total	Annually	≤0.1 mg/L
Total residual chlorine	Monthly	<0.1 mg/L
Bacteriological Testing:		
Heterotrophic platecount	Monthly	< 1000 CFU/mL
Water quality test	Annually	0.8 - 3.0 ratio

(iii) Each lot of laboratory detergent used on glassware that will be exposed to bacterial samples or cultures shall be tested to ensure that it is free of inhibitory residues.
(iv) Each batch of washed glassware shall be tested for possible acid or alkaline residue by testing one piece of glassware with a suitable pH indicator such as bromthymol blue.

(G) Selectivity. Confirmation / verification test shall be preformed as specified by the analytical method.

(H) Autoclaves. Records of autoclave operations including temperature and duration of sterilization runs shall be recorded.

(3) Radiological analysis. The following are the minimum quality control requirements for radiological testing:

(A) Method blanks, matrix spikes, laboratory control samples, and matrix spike duplicates or laboratory duplicates shall be performed at a frequency of one per batch.

(B) The laboratory shall calibrate all nuclear counters with NIST traceable standards. Calibration standards shall have the same general characteristics as the samples.

Performance checks and background measurements of counters shall be monitored with control and tolerance charts. Performance checks shall be conducted on a per use basis except for alpha spectroscopy counting efficiency which shall be performed on a monthly basis. Background measurements shall be conducted on a monthly basis except for proportional and scintillation counters which shall be performed on a per use basis. The same source used for calibrations shall be used for performance checks. When the performance check falls outside the tolerance charts, the instrument shall be re-calibrated.

(C) The laboratory shall initially establish Environmental Detection Limits (EDL) and Analytical Detection Limits (LD). EDL and LD shall be at the 0.95 or greater confidence level. EDL and LD shall be verified once per year.

(D) The laboratory shall trace all sources of method uncertainties and its propagation to reported values.

(E) Reference standards shall be NIST traceable. Reference standards shall have a certificate of calibration as described in ANSI N42.22 - 1995, section 8, Certificates.

(F) The laboratory shall only use the decay corrected certified value.

(4) Aquatic toxicity testing. The following are the minimum quality control requirements for toxicity testing:

(A) The laboratory shall demonstrate intra-laboratory test acceptability and precision according to the approved method before performing toxicity tests for permit compliance and on a continuous basis. If the permit identifies a different reference standard, dilution series, or frequency, the laboratory shall perform this test using the permit requirements.

(B) Initial and continuous test performance and precision shall be documented thought the use of quality control charts.

(C) Reference toxicant controls, and laboratory quality water shall be tested as provided in the approved methods.

(D) New batches of food used for culture maintenance and testing shall be compared to a food of known quality through a side by side performance comparison of test organisms.

(E) Reagents and reference toxicant standards. The laboratory shall prepare reference toxicant standards from chemicals which are analytical reagent grade or better. The preparation of all standards and reference toxicant shall be documented.

(F) Test organisms. All cultures used for testing shall be maintained as specified in the approved procedure. The age and the age range of the test organisms shall be as specified in the approved procedure. The test organisms shall be positively identified to species on an annual basis. The same batch of test organisms shall be used for a test when organisms are obtained from an outside source.

(G) Test sensitivity shall be calculated as the Minimum Significant Difference (MSD) as specified by the approved method.

(H) Test conditions.

(i) Light intensities shall be maintained as specified in the approved procedures. Measurements shall be made and recorded on a yearly basis.
(ii) The average daily temperature of the test solutions shall be maintained within 1°C of the selected test temperature for the duration of the test. The minimum frequency of measurement shall be once per 24 hour period. The test temperature for continuous flow toxicity tests shall be recorded and monitored continuously.
(iii) At a minimum, during chronic testing, Dissolved Oxygen and pH shall be measured daily in at least one replicate of each concentration.

(I) Holding times and preservation.

(i) The maximum holding time shall not exceed 36 hours without the permission of the department.
(ii) All samples shall be chilled to 4°C during collection or immediately after collection. They shall be maintained at 0.1° to 6°C and the temperature on arrival at the laboratory shall be no greater than 6°C. Samples hand delivered to the laboratory within one hour of collection may be accepted if there is evidence of chilling.

(5) When the approved method includes additional description of quality control measures, these measures shall be followed.

Part X - Records management

The laboratory shall have a record management system which will allow the historical reconstruction of all laboratory activities. The laboratory shall maintain a record to produce unequivocal and accurate documentation of all laboratory activities. The record keeping system shall facilitate the retrieval of all documentation for inspections and verifications by the laboratory personnel and the accreditation officer. Records shall be kept by the laboratory for not less than five years or as specified by the safe drinking water act, the clean water act, and the resource conservation and recovery act. These records shall include:

(1) Personnel records. These records shall include the following:

(A) Personnel qualifications, and experience.

(B) Personnel training (equipment, technic, procedures, ethical, and legal).

(C) Personnel initial and continuing performance. Documentation of work cell performance when applicable.

(D) Documentation that technical personnel have read, understood and agreed to perform the most recent version of the test method.

(2) Laboratory facilities. Documentation of environmental conditions when required by the approved method.

(3) Equipment, reference materials, reagents, supplies, and reference standards.

(A) Documentation on all reference material and laboratory equipment shall include:

(i) the name of the item;
(ii) the manufacture's name, identification and serial number;
(iii) date received and date placed in service;
(iv) condition when placed in service (new, used, re-conditioned), if available;
(v) current location, when appropriate;
(vi) copies of manufacturer's instruction manual when available;
(vii) details of maintenance; and
(viii) dates and results of calibrations and/or verifications;
(ix) history of any damage, malfunction, modifications or repairs.

(B) Documentation on laboratory support equipment shall also include the following:

(i) records of instrument performance;
(ii) when in use, records of established correction factors used for the correction of measurements made with the equipment;
(iii) accuracy checks of volumetric dispensing devices;
(iv) certificates of accuracy for glass microliter syringes;
(v) for microbiological testing the date, content, sterilization time, temperature, total cycle time, and analyst's initials for each autoclave cycle; This shall include the temperature readings obtained from a maximum-temperature-registering thermometer or a continuous temperature recording device and the use of biological indicators;
(vi) for chemical testing the sample identification, date, temperature, the cycle time, and pressure of the autoclave;
(vii) temperature of microbiological incubators and waterbath;
(viii) checks of mechanical timers.

(C) For each reference standard, the laboratory shall retain certificates.

(D) Reagents and standards. The laboratory shall retain records for all standards including the manufacturer/vendor, the manufacturer's certificate of purity, the date of receipt, recommended storage conditions, and expiration date.

(E) Preparation of reagents and standards. The laboratory shall maintain a preparation log which shall include traceability to purchased reagents and standards, reference to method of preparation, date of preparation, expiration date (if applicable), and name of analyst. Container of prepared solutions shall have an identifier and an expiration date, and shall be linked to the preparation log.

(F) The quality of laboratory water shall be documented.

(3) Sample collection, preservation, holding time, and handling. The laboratory shall maintain sufficient records to demonstrate samples are properly collected, handled, and preserved. All records shall be linked to the sample identification. Records shall include:

(A) Sample information.

(i) Date, place, and time of sampling and the name of the person who collected the sample;
(ii) laboratory sample identification and field sample identification (when available);
(iii) date and time of sample receipt;
(iv) person responsible for logging the sample;
(v) analysis or analytical method requested;
(vi) laboratory name or place of analysis; and
(vii) sampling kit code (when applicable).

(B) Sample collection forms.

(C) Chain of custody forms (if available).

(D) Sample receiving log.

(E) Documentation of appropriate sample disposal.

(F) All information regarding sample integrity and sample acceptance as defined under sample collection, preservation, holding times and handling of this document.

(4) Analytical methods. The laboratory shall maintain the following information as part of the analytical records to allow the reconstruction of data:

(A) Sample identification with date and time of sample preparation and analysis. Initials or signature of the analyst involved in preparation of samples and the analyst involved in the analysis of samples.

(B) The analytical method used both for sample preparation and analysis.

(C) Results of the analysis and the raw data generated. This shall include the calibration used for quantitation of sample concentration and identification of the instrument used for the analysis. Sample volume or sample weight shall be documented.

(D) Instrument operating conditions and instrument responses.

(E) Results of quality control and acceptance criteria.

(F) Calculations used for data reduction.

(G) Validation of data and initial or signature of the data reviewer.

(H) Documentation of initial demonstration of capability for methods and initial demonstration of capability certificate.

(I) Documentation of the procedure used for method validation with all data necessary to reproduce the analytical results shall be retained by the laboratory.

(5) Laboratory Quality Assurance Program.. The following items shall be kept and documented by the laboratory:

(A) Documentation of laboratory policies, laboratory administrative procedures, analytical procedures, quality assurance manual and/or related quality documents.

(B) All reviews, audits, audit findings, and corrective action taken shall be documented by the laboratory. Copies of any written notifications made to the department and/or the client when an audit or review determines the validity of data is compromised.

(C) Copies of historical SOPs.

(6) Instrument Calibrations. The following items shall be documented by the laboratory:

(A) Calibration procedures.

(B) All raw data necessary for the reconstruction of initial calibrations.

(C) All raw data necessary for the reconstruction continuing calibration verification.

(7) Quality Control.

(A) Chemical testing.

(i) All quality control results and results of data quality indicators shall be documented. There shall be a correlation between quality controls analyzed by the laboratory and the samples associated with them. Spiking components and concentrations shall be documented.

(ii) Procedures used for determination of detection limits and all raw data necessary for the reconstruction of the detection limits shall be retained.
(iii) Retention time windows, mass tuning results and confirmation shall be fully documented when in use by the laboratory. Documentation of clients request for the laboratory not to conduct confirmation on their samples shall be retained.

(B) Microbiological testing.

(i) All quality control results shall be documented. This shall include blanks, sterility checks, positive and negative controls, duplicates, water quality checks, inhibitory residue test, acid/alkalinity tests and demonstration of method proficiency.
(ii) All certificates of quality supplied by the manufacturer shall be retained.
(iii) The type of media, the lot number, date received and results of the pH verification shall be documented.

(C) Radiological testing.

(i) All quality control results and results of data quality indicators shall be documented. There shall be a correlation between quality controls analyzed by the laboratory and the samples associated with them. Spiking components and concentrations shall be documented.
(ii) Procedures used to establish EDL and LD and all raw data necessary for the reconstruction shall be documented.

(D) Aquatic toxicity testing.

(i) All quality control results and results of data quality indicators shall be documented. This shall include comparison of newly prepared food batches, initial and continuous test performance.

(8) Reports. The laboratory shall maintain copies of all reports, copies of corrected or modified reports, and copies of any written notification sent to a client about the reported data.

(9) Proficiency testing. The laboratory shall maintain all information resulting from the analysis of proficiency testing samples. This shall include copies of the proficiency testing study

reporting forms, analytical data, correspondence and documentation provided by Proficiency Testing providers, and documentation of investigations and corrective actions for failed studies.

(10) General requirements for records management.

(A) All data not generated electronically, shall be recorded in a legible manner using permanent ink. All corrections to records shall be made by crossing the error with a single line, the date of the correction shall be noted and the individual making the correction shall initial or sign the record.

(B) Records shall be stored securely and safely to prevent loss or potential tampering.

(C) Computer and electronic systems used by the laboratory for recording, processing, reporting, storage or retrieval of data shall comply with sections 8.1 trough 8.11 of EPA document “2185 - Good Automated Laboratory Practices” (1995).

(D) All electronic hardware and software to reconstruct the analytical data shall be available.

(E) Records of record storage and access of these records.

(F) Provisions for transfer of records to another owner.

(G) Records of complaint and action taken.

(H) Correspondence relating to laboratory activities for a specific project.

(I) A log of names, initials and signatures for all individuals who are responsible for signing or initialing any laboratory records.

Part XI - Reporting

(1) The laboratory shall include the following information when reporting analytical results:

(A) Report title, name and address of the laboratory, and accreditation number;

(B) location of sample test;

(C) contact person and phone number at the laboratory;

(D) unique identification of the report;

(E) report pages shall be numbered. The laboratory shall provide the total number of pages on the report;

(F) identification of the client or project name, or both (when applicable);

(G) identification of the sample included with field sample identification when available;

(H) for whole effluent toxicity the statistical package used to provide the results;

(I) date the sample was received, date and time of collection, date(s) of analysis. The time of analysis is required when the holding time for that analysis is less than 72 hours;

(J) identification of the method used or method number;

(K) reference to sampling procedure when relevant;

(L) any modifications made to the approved method during analysis of the sample;

(M) data qualifiers to describe sample receiving and analytical conditions;

(N) analytical data shall be reported in units consistent with monitoring program requirements, and calculations made on a dry weight or wet weight basis shall be identified;

(O) signature and title or electronic identification of person accepting responsibility for the content of the report, and date issued;

(P) when the report contains analytical results from a sub-contract laboratory, the full name and Kansas accreditation number of the sub-contract laboratory shall be clearly reported, and the analysis performed by the sub-contract laboratory shall be identified;

(Q) reports issued by the laboratory shall remain unchanged, any reports issued by the laboratory with amendments to a previous report, shall be clearly identified as an amended report;

(R) a statement of the estimated uncertainty of the test results, when required by the project;

(S) a statement to the effect that the results relate only to the items tested or to the samples as received by the laboratory, when applicable;

(T) a statement that the report shall not be reproduced except in full without the approval of the laboratory, when applicable;

(U) clear indication of numerical results with values outside of the laboratory's quantitation limits;

(V) the laboratory shall certify that the test results meet the requirements of the National Environmental Laboratory Accreditation Conference or a reason and/or justification shall be provided if they do not;

(W) the laboratory shall differentiate between accredited and non-accredited parameters.

(2) When the laboratory is required by the monitoring program to report data in a report form provided by the program, the reporting requirements listed above may not apply. The following requirements apply to these facilities:

(A) the laboratory shall maintain records of all applicable elements listed above.

(B) the applicable elements listed above shall be available to the individual within the organization preparing report forms provided by the program.

(C) the laboratory management shall ensure all appropriate items are included in the report forms provided by the program.

(3) Any problems identified with the validity of the analytical results shall be reported by the laboratory.

Part XII - Proficiency testing

During participation in a proficiency testing study and before the results of the study are released, the laboratory shall comply with the following conditions:

(1) The laboratory shall analyze proficiency testing samples in the same manner and at the same frequency as environmental samples;

(2) The laboratory shall not send proficiency testing samples to another laboratory for any analysis for which it seeks accreditation;

(3) The laboratory shall not knowingly accept proficiency testing samples from another laboratory for any analysis for which the sender is seeking accreditation;

(4) The laboratory personnel shall not exchange or offer information about proficiency testing sample results with personnel from another laboratory; and

(5) The laboratory personnel shall not attempt to obtain the true values of any proficiency testing samples from the provider.

Part XIII - Use of accreditation by accredited laboratories.

(1) An accredited laboratory shall display the most current certificate or parameter list in a prominent place in the laboratory facility.

(2) An accredited laboratory shall make accurate statements concerning their accreditation.

(3) An accredited laboratory shall include the accreditation number issued by the department when making reference to their accreditation status or when using the department's name in any literature such as catalogs, advertising, business solicitations, proposals, quotations, or other materials.

(4) An accredited laboratory shall differentiate between accredited and non-accredited parameters when making reference to their accreditation status or when using the department's name in any literature such as catalogs, advertising, business solicitations, proposals, quotations, or other materials.

(5) An accredited laboratory shall not use their accreditation to imply endorsement by the department.

(6) An accredited laboratory shall return any certificates and parameter lists issued by the department upon suspension or revocation of their accreditation, when requested by the department.

(7) Upon suspension or revocation, an accredited laboratory shall discontinue the use of any literature referencing their past accreditation status.

APPENDIX A

DEMONSTRATION OF CAPABILITY

DEMONSTRATION OF CAPABILITY
PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a significant change in instrument type, personnel or test method (see "Standards for Accreditation of Environmental Laboratories" November 1998, Part VI, and NELAC 5.10.2.1). Note: In laboratories with specialized "work cells" (a well defined group of analysts that together perform the method analysis), the group as a unit must meet the above criteria and this demonstration must be fully documented.

In general, this demonstration does not test the performance of the method in real world samples, but in the applicable and available clean matrix (a sample of a matrix in which no target analytes or interferences are present at concentrations that impact the results of a specific test method), e.g.,
water, solids, biological tissue and air. However, before any results are reported using this method,
actual sample spike results may be used to meet this standard, i.e.,at least four consecutive matrix spikes within the last twelve months. In addition, for analytes which do not lend themselves to spiking, e.g., TSS, the demonstration of capability may be performed using quality control samples.

All demonstrations shall be documented through the use of the attached form in this appendix. Note: For analytes for which spiking is not an option and for which quality control samples are not readily available, it is the responsibility of the laboratory to document that other approaches to DOC are adequate, this shall be documented under the demonstration of capability in the laboratory's Quality Manual.

The following procedure was adapted from the EPA test methods published in 40 CFR Part 136, Appendix A:

a) A quality control sample shall be obtained from an outside source. If not available, the QC sample may be prepared by the laboratory using stock standards that are prepared independently from those used in instrument calibration.

b) The analyte(s) shall be diluted in a volume of clean matrix sufficient to prepare four aliquots at the concentration specified, or if unspecified, to a concentration approximately 10 times the method-stated or laboratory-calculated method detection limit.

c) At least four aliquots shall be prepared and analyzed according to the test method either concurrently or over a period of days.

d) Using all of the results, calculate the mean recovery ($\bar{x}$) in the appropriate reporting units (such as mg/L) and the standard deviations of the population sample (n-1) (in the same units) for each parameter of interest. When it is not possible to determine mean and standard deviations, such as for presence absence and logarithmic values, the laboratory will assess performance against established and documented criteria.

e) Compare the information from (d) above to the corresponding acceptance criteria for precision and accuracy in the test method (if applicable) or in laboratory-generated acceptance criteria (if there are not established mandatory criteria). If all parameters meet the acceptance criteria, the analysis of actual samples may begin. If any one of the parameters do not meet the acceptance criteria, the performance is unacceptable for that parameter.

f) When one or more of the tested parameters fail at least one of the acceptance criteria, the analyst must proceed according to 1) or 2) below.

1) Locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c) above.
2) Beginning with c) above, repeat the test for all parameters that failed to meet criteria. Repeated failure, however, will confirm a general problem with the measurement system. If this occurs, locate and correct the source of the problem and repeat the test for all parameters of interest beginning with c).

CERTIFICATION STATEMENT

The following certification statement shall be used to document the completion of each demonstration of capability. A copy of the certification statement shall be retained in the personnel records of each affected employee.

Demonstration of Capability
Certification Statement

Date: Page __of __
Laboratory Name:
Laboratory Address:
Analyst(s) Name(s):
Matrix:
(examples: laboratory pure water, soil, air, solid, biological tissue)
Method number, SOP#, Rev#, and Analyte, or Class of Analytes or Measured Parameters
(examples: barium by 200.7, trace metals by 6010, benzene by 8021, etc.)

The undersigned, CERTIFY that:

1. The analysts identified above, using the cited test method(s), which is in use at this facility for the analyses of samples under the K.A.R. 28-15-35 and the National Environmental Laboratory Accreditation Program, have met the Demonstration of Capability.

2. The test method(s) was performed by the analyst(s) identified on this certification.

3. A copy of the test method(s) and the laboratory-specific SOPs are available for all personnel on-site.

4. The data associated with the demonstration capability are true, accurate, complete and self-explanatory (1).

5. All raw data (including a copy of this certification form) necessary to reconstruct and validate these analyses have been retained at the facility, and that the associated information is well organized and available for review by authorized assessors.

_____	_____	_____
Technical Director's Name and Title	Signature	Date
_____	_____	_____
Quality Assurance Officer's Name and Title	Signature	Date

This certification form must be completed each time a demonstration of capability study is completed.
(1) True: Consistent with supporting data.
Accurate: Based on good laboratory practices consistent with sound scientific principles/practices.
Complete: Includes the results of all supporting performance testing.
Self-Explanatory: Data properly labeled and stored so that the results are clear and require no additional explanation.

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